Remarks

Claims 12 and 20-25 are currently pending and under examination. Claim 12 has been amended. A supplemental Sequence ID Listing accompanies this response. The following rejections are at issue and are set forth by number in the order in which they are addressed:

1. Claims 12 and 20-25 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite;
2. Claims 12 and 20-25 are rejected under 35 U.S.C. §112, first paragraph, as allegedly being not enabled;
3. Claims 12 and 20-25 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description;
4. Claims 12 and 20-25 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Harper et al., U.S. Pat. Pub. 2002/0160378.

Unless otherwise noted, the claims have been cancelled or amended to further Applicant's business interests and the prosecution of the present application in a manner consistent with the PTO's Patent Business Goals (PBG; 65 Fed. Reg. 54603 (September 8, 2000), and not in acquiescence to the Examiner's arguments and while reserving the right to prosecute the original (or similar) claims in the future. None of the claim amendments made herein are intended to narrow the scope of any of the amended claims within the meaning of *Festo Corp. v. Shokestu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) or related cases.

1. The Claims are Definite

Claims 12 and 20-25 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The claims have been amended to refer to DNA sequences, thus rejection is moot.

2. The Claims Are Enabled

Claims 12 and 20-25 are rejected under 35 U.S.C. §112, first paragraph, as allegedly being not enabled. Applicant contends that the Examiner has not established a *prima facie* case

of nonenablement. The standard to be applied in assessing enablement is whether the experimentation needed to practice the claimed invention is undue or unreasonable. *See* TRAINING MATERIALS FOR EXAMINING PATENT APPLICATIONS WITH RESPECT TO 35 U.S.C. SECTION 112, FIRST PARAGRAPH-ENABLEMENT CHEMICAL/BIOTECHNICAL APPLICATIONS, *citing In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). When applying this standard, the burden is on the Examiner to make a *prima facie* case of non-enablement that is well grounded in scientific reasoning or evidence. *See In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993); *See also* MPEP §706.03 and §2164.04. This is because without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling (*Wright,* 27 USPQ2d at 1513).

Claim 12 now specifically provides that the transcription regulating protein is encoded by a sequence at least 95% homologous to SEQ ID NO:1 and that that "the protein is capable of selectively binding to a DNA regulatory sequence comprising CAACA so that a cold or dehydration regulatory gene is expressed." Thus, the claims provide a functional limitation that is easily tested by one of skill in the art. The Examiner has not addressed this argument in the current Office Action. Applicants respectfully submit that, given the teachings of the specification, one of skill in the art would be able to easily identify functional variants that can bind to a DNA regulatory sequence comprising CAACA in a plant. Because the Examiner has not considered this limitation, the Examiner's argument is not well grounded in scientific reasoning or fact and a *prima facie* case of nonenablement has not been established.

3. The Claims Have An Adequate Written Description

Claims 12 and 20-25 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description.

Again, Applicants respectfully refer the Examiner to the USPTO's "Synopsis of Application of Written Description Guidelines", Example 14, pages 53-55. The claim of Example 14 recites a protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A->B. The disclosure of Example 14 provides a single species (SEQ ID NO:3) that has actually been reduced to practice, and describes an assay for identifying the variants having the desired catalytic activity. The analysis considers (1) whether the members of genus vary substantially from each other; and (2) whether

the disclosed species is representative of the members of the genus; in order to determine whether one of skill in the art would determine if the applicant was in possession of the necessary common attributes possessed by the members of the genus.

For Example 14, it was determined that the member species did not substantially vary since the variants have 95% identity or greater to the reference sequence, and also possess the catalytic activity. It was also determined that the disclosed species was representative since all members must have at least 95% structural identity to SEQ ID NO:3. The analysis determined that one of skill in the art would conclude that the applicant was in possession of the necessary common attributes possessed by the members of the genus, and therefore the disclosure in this Example meets the written description requirement.

Applicants submit that the subject matter of Claim 12 of instant application can be analyzed in a similar manner to that provided in Example 14 of the Written Description Guidelines. Claim 12 requires 1) at least 95% homology to SEQ ID NO:1 and 2) that "the protein is capable of selectively binding to a DNA regulatory sequence comprising CAACA in the plant which regulates expression of one or more environmental stress tolerance genes in the plant." In Claim 12, just as in the Written Description Guidelines, the disclosed species is representative because all members of the genus must have 95% homology and because they must exhibit binding to a defined sequence.

The Examiner first argues that "it is noted that the claims recite "85%", which encompasses a much larger genus than 95%." Office Action p. 4. This argument has been addressed by the amendment. The Examiner then argues that "the specification does not teach the structures within SQ ID NO:1 or 2 that are required for functionality and which must be shared by all species of the claimed genus." Office Action p. 4. With all due respect, this argument is completely inconsistent with the cited written description guideline, which made no requirement of showing what sequences within the specified sequence were required for function. The Examiner is creating distinctions that do not exist in the guidelines. The structural/functional limitation required by the Examiner is met by specifying that member s of the genus must have 95% homology to the reference sequence and also must be capable of selectively binding to a DNA regulatory sequence comprising CAACA in the plant which regulates expression of one or more environmental stress tolerance genes in the plant.

The Examiner further argues that "proteins that are less than 100% identical to a protein

encoded by SEQ ID NO:1 may bind to CAACA but still unable to regulate the expression of cold and dehydrate genes, because binding to said regulatory sequence alone will not determine its effective regulatory response." Office Action p. 5. The claims have been amended to specify that the binding results in expression of a cold or dehydration regulatory gene. Thus, this argument appears to be moot as proteins that do not accomplish the claimed function are excluded from the claim.

4. The Claims Are Not Anticipated

The Examiner has rejected Claims 12 and 20-25 under 35 U.S.C. §102(e) as allegedly being anticipated by Harper et al., U.S. Pat. Pub. 2002/0160378. As established in Aplicants previous response, when the actual data is analyzed, it becomes clear that Harper et al. do not teach the use of SEQ ID NO:1 of the instant application for inducing freezing or drought tolerance. The Examiner's attention is respectfully directed to Column 80, table 7 of Harper et al. SEQ ID NO:2316 is identified in Table 7 as being a saline stress responsive sequence. SEQ ID NO:2316 is not identified as a cold responsive sequence in Table 3 (columns 72-75) or as an osmotic stress related sequence in Table 11 (column 82), or as cold and saline responsive sequence in able 18 (column 86). Thus, Harper et al. does not teach the use of SEQ ID NO:2316 to induce freezing and drought tolerance.

In response, the Examiner argues that "Harper et al. specifically teach that the polynucleotides taught in the reference would confer any type of stress tolerance that includes cold and dehydration related stresses (Paragraph 0031)." However, Paragraph 0031 does not teach that all of the more than 4000 sequences disclosed in Harper et al. all confer multiple types of stress tolerance. As described above, it is necessary to examine the actual data to determine what stress tolerances the individual sequences allegedly confer. To be clear, Paragraph 0031 provides the following:

> [0031] The present invention also relates to a method of identifying a polynucleotide that modulates a stress response in a plant cell. In one embodiment the method comprises determining gene expression in a plant exposed to at least one stress to produce an expression profile and identifying sequences whose expression is altered at least two fold compared to plants not exposed to the stress. Such an expression profile can be obtained, for example, by contacting an array of probes representative of a plant cell genome with nucleic acid molecules expressed in a plant cell exposed to the stress; and detecting one

> or more nucleic acid molecules expressed at a level different from a level of expression in the absence of the stress. The method can further comprise introducing the differentially expressed nucleic acid molecule into a plant cell; and detecting a modulated response of the genetically modified plant cell to a stress, thereby identifying a polynucleotide that modulates a stress response in a plant cell. The stress can be any stress, for example, an abiotic stress such as exposure to an abnormal level of cold, osmotic pressure, and salinity. The contacting is under conditions that allow for selective hybridization of a nucleic acid molecule with probe having sufficient complementarity, for example, under stringent hybridization conditions. Expression of the nucleic acid molecule can increase or decrease the tolerance of the plant cell to the stress, and the nucleic acid molecule can be expressed at a level that is less than or greater than the level of expression in the absence of the stress.

This paragraph merely provides that the polynucleotides identified in the methods of the invention can modulate *any* stress. The specific stress that a particular sequence modulates are not identified. Thus, this paragraph is not relevant to the actual function of SEQ ID NO:1 and is not relevant to anticipation of the instant claims.

The Examiner goes on to argue that "the property of regulating cold and dehydration genes is inherent to the method used by Harper et al. as SEQ ID NO:2316 (100%) identical to instant SEQ ID NO:1) encodes a protein that has the inherent property of binding to CAACA regulatory sequence of cold and dehydration genes." The Examiner's argument is without merit. It well established that claims to new uses of known compositions are patentable:

> We are of the opinion that appellants have invented a new use for a known compound (or at least a group of compounds including known compounds). In claim 21 this new use has been properly claimed as a process under 35 U.S.C. 100(b).

In re Riden, 138 U.S.P.Q. (BNA) 112, (C.C.P.A. 1963). In the instant application, the claims are not directed to the composition, the claims are properly directed to a process limited to the new use discovered by Applicants. The Examiner's anticipation by inherency fails to take into account the limitation to the newly discovered use (i.e., using the sequence to cause expression of a cold or dehydration regulatory gene.)

Conclusion

All grounds of rejection and objection of the Office Action of March 21, 2006 having been addressed, reconsideration of the application is respectfully requested. It is respectfully

submitted that the invention as claimed fully meets all requirements for patentability and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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